

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

NORTH BREVARD COUNTY HOSPITAL
DISTRICT D/B/A PARRISH MEDICAL
CENTER,

Plaintiff,

-against-

C.R. BARD, INC.; BARD ACCESS
SYSTEMS, INC.,

Defendants.

Case No.: 1:20-CV-0363 (TJM/CFH)

COMPLAINT

JURY TRIAL DEMANDED

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Plaintiff, North Brevard County Hospital District d/b/a Parrish Medical Center, individually and on behalf of a class of direct purchasers of peripherally inserted central catheters that Defendants sold, alleges as follows.

NATURE OF THE ACTION

1. Defendants, C.R. Bard, Inc. and Bard Access Systems, Inc. (collectively “Bard”), have unlawfully and anticompetitively tied its sales in a market for peripherally inserted central catheters (“PICCs”) to its sales in a distinct and separate market for tip-location systems. Bard has market power in both markets and has used its power in the former to coerce anticompetitive sales in the latter. As a consequence, Bard has harmed PICC price and other competition, and hospitals and other purchasers have paid Bard supra-competitive prices for its PICCs.

2. Defendants’ conduct has also denied hospitals the choice of PICCs superior to Bard’s PICCs in the suppression of dangerous blood clotting. Bard competitor AngioDynamics, Inc. sells a PICC catheter that uses superior innovative technology with a significant positive impact on patient outcomes with respect to blood clotting. Bard’s PICC technology is inferior. In *AngioDynamics, Inc. v. C.R. Bard, Inc.*, Civ. No. 1:17-CV-0598 (BKS/CFH), filed in this Court, AngioDynamics alleges that Bard’s conduct in this regard has violated the Sherman Act, harming competition in the relevant market and causing injury to AngioDynamics.

3. A PICC is a central venous catheter placed into a peripheral vein, usually the basilic vein in the arm, and passed to the distal superior vena cava, near the junction of the right atrium of the heart. Clinicians use PICCs to administer fluids, medications, and nutrients; to sample blood; and to power-inject contrast media. The PICC is a thin, soft, flexible tube. The PICC may remain in place for an extended period if no complications arise.

4. Separate technologies that provide information concerning the location of the tip of the PICC are essential to the use of any PICC. These technologies assist clinicians in navigating the PICC through the venous system so it reaches the proper place in the body and to confirm that the tip of the PICC has been positioned in the proper place. Improperly positioned PICCs may cause complications and serious health risks, some of which can be fatal. Historically, a chest x-ray or fluoroscopy determined the final PICC location. Clinicians today typically use tip-location systems, tracking the PICC as it moves.

5. Many tip-location systems use a patient's electrocardiographic ("ECG") waveform to determine a PICC's final position in relation to the heart. Tip-location systems have revolutionized PICC placement because they serve as a less expensive, less time-consuming, and more accurate alternative to chest x-rays or fluoroscopy to determine final PICC position. If a tip-location system includes navigation technology, the technology can be used to guide the placement of the PICC by gathering information regarding its movement toward its destination.

6. Bard possesses market power in the market for tip-location systems. Bard is the largest player in this market, and its market share exceeds 70 percent.

7. Bard's tip-location systems are sold under the brand names Sherlock 3CG® Tip Confirmation System ("Sherlock 3CG") and Sherlock® II Tip Location System ("Sherlock II"). Bard was the first company to come to market with navigation technology. Bard's Sherlock 3CG system is the first and only tip-location system on the market that includes three complementary technologies to facilitate PICC placement: (i) ultrasound technology for PICC insertion into a suitable vein, (ii) magnetic-tracking technology for PICC navigation through the venous system, and (iii) ECG technology for PICC tip location within the superior vena cava.

Bard's Sherlock 3CG system is thus widely regarded as providing the most advanced technology available and the greatest ease of use for clinicians placing PICCs.

8. Bard has illegally used its firmly established, dominant position in the market for tip-location systems to stifle competition in the market for sale of PICCs. Bard has done so by illegally tying its market-leading tip-location systems to its PICCs. If a customer wants to use one of Bard's superior tip-location systems, it must also buy Bard's PICCs to obtain the proprietary Bard stylets necessary to operate the tip-location systems. In short, Bard forces customers to buy its PICCs to acquire its tip-location systems.

9. By leveraging its market power in the market for tip-location systems to expand its sales of PICCs, Bard has harmed PICC competition, including price competition, and suppressed free hospital choice of the superior AngioDynamics PICC technology. As a result of Bard's exclusion of PICC competition, in the exercise of its market power, direct purchasers of Bard's PICCs have paid supra-competitive prices.

10. Bard has no legitimate business or health reason to tie its market-leading tip-location systems to its PICCs. Bard obtained FDA approval to sell its proprietary stylet allowing use of its systems separately from its PICCs, in "single-sterile" style, which would allow its systems to be used with any company's PICCs. Bard has sold the stylet in this way to one large purchaser with significant leverage, the Cleveland Clinic, allowing the Clinic to use a Bard tip-location system and AngioDynamics' BioFlo PICCs together. Bard has not made this option available to any other purchaser, and Bard requires any purchaser interested in acquiring and using its systems to purchase and use Bard's PICCs.

JURISDICTION AND VENUE

11. Plaintiff brings suit under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, to recover treble damages, injunctive relief, costs of suit, and reasonable attorneys' fees arising from Defendants' violations of Sections 1 and 2 of the Sherman Act, 28 U.S.C. §§ 1, 2.

12. Subject matter jurisdiction is proper under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, and 28 U.S.C. §§ 1331 and 1337.

13. The medical devices at issue are sold in interstate commerce, and the alleged unlawful activities have occurred in, and have substantially affected, interstate commerce.

14. Defendants are subject to personal jurisdiction in this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, because they may be found in this district and they transact business in this district.

15. Venue is proper pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391 because Defendants transact business in this district, a substantial part of the events giving rise to purchaser claims occurred in this district, and AngioDynamics resides in this district.

PARTIES

16. Plaintiff, North Brevard County Hospital District d/b/a Parrish Medical Center ("Parrish"), is a governmental entity located at 951 North Washington Ave., Titusville, Florida 32796. Plaintiff has directly purchased PICCs from Bard since 2013.

17. Defendant C.R. Bard, Inc. ("C.R. Bard") is a company organized under the laws of New Jersey and headquartered in Murray Hill, New Jersey. C.R. Bard is a publicly traded provider of vascular access, oncological, urological, and surgical medical devices. C.R. Bard manufactures PICC catheters.

18. Defendant Bard Access Systems, Inc. (“Bard Access”) is a company organized under the laws of Utah and headquartered at Salt Lake City, Utah. Bard Access is a subsidiary of C.R. Bard and is listed on C.R. Bard’s website as a “division” of C.R. Bard. Bard Access primarily distributes PICC catheters manufactured by C.R. Bard.

19. On April 23, 2017, Becton, Dickinson and Company (“Becton”), another medical-device manufacturer, and Bard announced that they had reached an agreement under which Becton would acquire Bard for \$24 billion. In a presentation to investors, the companies stated that together they would have about \$16 billion in annual revenue and 65,000 employees with a presence in nearly every country around the world.

RELEVANT MARKETS

Product Market for the Sale of Tip-Location Systems

20. The relevant product for the sale of tip-location systems (“the tip-location market”) encompasses sales to hospitals and other purchasers of tip-location systems (including stylets) reasonably interchangeable in use with those sold by Bard.

21. While tip-location systems are designed to be used with PICCs, they are sold in a separate market from the market for the sale of PICCs. The latter products perform a different medical function from tip-location systems and are not reasonably interchangeable in use with tip-location systems. They are product complements to tip-location systems.

22. Industry organizations recommend using tip-location systems over other, traditional methods of locating PICC placement, such that tip-location systems are the standard of care in the industry. Tip-location systems have largely displaced the use of x-rays and fluoroscopy to locate PICC placement.

Product Market for the Sale of PICCs

23. The relevant product market for the sale of peripherally inserted central catheters (“the PICC market”) encompasses sales to hospitals and other purchasers of PICCS reasonably interchangeable in use with those sold by Bard.

24. PICCs are thin, soft, flexible tubes inserted into the body through a vein, typically in the upper arm, and passed to the superior vena cava. PICCs are used to administer fluids, medications and nutrients; to sample blood; and to power-inject contrast media.

25. PICCs are sold in a separate market than the tip-location market. PICCs historically have been sold on a standalone basis. They are complements to tip-location systems rather than substitutes and perform a different medical function. PICCs are a widely used method of vascular access, with clinicians placing approximately 2.7 million PICCs every year.

26. PICCs are not reasonably interchangeable with other types of vascular catheters for the multi-day period for which PICCs are typically used. Short peripheral intravenous venous catheters are typically used for very short-term treatments, and implantable vascular ports are typically used for long-term treatments.

Geographic Markets

27. The geographic scope of both the tip-location market and PICC market, as described further below, is the United States.

MARKET POWER

Bard’s Market Power in the Tip-Location Market

28. Bard has market power in the market for tip-location systems. It was the first company to market tip-location systems with navigation technology. Tip-location systems have become the industry standard of care in PICC placement, and at least one recent survey suggests

that approximately 75 percent of tip-location purchasers would not buy a tip-location system that lacked navigation. In addition, Bard is the only company on the market with a tip-location system that provides ECG tip location technology, navigation technology, and ultrasound technology. This combination of technologies provides the highest quality in PICC placement, thus providing the greatest ease of use for clinicians. A Bard tip-location system includes the proprietary stylet necessary to operate the system as a component. A tip-location system and stylet comprise one product because they are designed to function together and one cannot function without the other.

29. There are high barriers to entry in the tip-location market. These include both technological and regulatory barriers. Entry into the market requires significant research and development – including hardware and software design, clinical testing, market research, and FDA approval – prior to any sales. As a result, the time to market is lengthy. The level of investment required is high.

30. Bard's share of the tip-location market exceeds 70 percent. Very few Bard competitors have entered the tip-location market. Bard has always maintained a dominant share of the tip-location market.

Bard's Market Power in the PICC Market

31. In substantial part by virtue of its unlawful tying of the sale of its tip-location systems to the sale of its PICCs, Bard has the power to control price or exclude competition in the PICC market. Bard's share of the PICC market exceeds 70 percent.

32. After the advent of AngioDynamics' superior BioFlo PICCs, Bard has nevertheless expanded its dominant position in the PICC market. As a consequence, AngioDynamics, a product innovator, has been effectively shut out of a substantial portion of the market for PICCs, and price competition from it and other competitors has decreased.

33. In addition to Bard's exclusionary tying, there are high technology and regulatory barriers to entry into this market. As evidenced in part AngioDynamic's development of superior anti-clotting properties, entry requires substantial research and development and FDA approval. The level of investment is high.

EXCLUSIONARY CONDUCT

Bard's Tying of Its PICCs and Its Tip-Location Systems

34. Bard has used its market power in the tip-location market to coerce purchases of its PICCs in the PICC market. Bard has exploited its control over the tip-location market to force purchasers, members of the Class, to purchase Bard's PICCs, which the purchasers would have preferred not to purchase or to purchase otherwise and on different terms.

35. Bard's Sherlock 3CG system and its Sherlock II tip-location systems cannot be utilized without Bard's proprietary stylet. Bard only sells this stylet preloaded in its PICCs. Accordingly, to use one of Bard's tip-location systems, one must also purchase its PICCs to obtain the stylets necessary to operate the system.

36. There is no legitimate reason, technological, business, or otherwise, that Bard must tie the sale of these separate products. Bard does so to drive sales of its inferior, less safe PICCs, thereby injuring competition in the PICC market. Any justification Bard has for this tying is far outweighed by the anti-competitive effects in the market for PICCs.

37. Bard itself has acknowledged that there is no reason that its tip-location systems and its PICCs cannot be sold separately such that Bard's market leading tip-location system could be used with AngioDynamics' innovative, best-in-class PICCs.

38. Bard sought FDA approval to sell its proprietary stylets single-sterile, and the FDA granted section 510(k) premarket-notification clearance for such sales. In its section 510(k)

clearance letter, the FDA stated that Bard's stylet "may now be used with specific Bard catheters as well as any open-ended, non-valved, polyurethane peripherally inserted central catheter that meets the dimensional specifications of the stylet (0.020 in minimum lumen diameter)."

39. Bard has previously sold its stylets single-sterile to one of the leading medical centers in the United States, the Cleveland Clinic. Given its prominence, the Clinic has significant purchasing leverage. The Clinic had trialed BioFlo PICCs and noted a significant reduction in upper-extremity deep-vein thrombosis, discussed further below, in patients using BioFlo PICCs versus polyurethane PICCs. The Clinic thereafter successfully requested to purchase Bard's stylets single-sterile so that it could use AngioDynamics' BioFlo PICCs with the Bard Sherlock 3CG tip-location system.

40. This is the only time that Bard has sold its stylets single-sterile in order to allow its tip-location systems to be used with another company's PICCs. Other institutions have requested that Bard sell its stylets single-sterile to them, and Bard has refused their requests. Aside from its sales to the Cleveland Clinic, Bard has always refused to sell its stylet single-sterile, despite having the FDA approval to do so.

41. Because Bard refuses to sell the stylet necessary to operate their systems single-sterile, Bard's large market share in the tip-location market means that the tie has a substantial impact on the PICC sales of AngioDynamics and Bard's other competitors.

42. Bard is the only seller of tip-location systems that has a "closed" system, in which the tip-location system is tied to its PICCs and cannot be purchased separately. No other seller of tip-location systems thus ties its tip-location systems to its PICCs. Instead, they all have "open" systems in which they sell their tip-location systems separately, or offer to do so, and thus allow them to be used with any manufacturer's PICCs.

43. Bard has market power in the tip-location market. The tying product is Bard's tip-location system. A Bard tip-location system includes the proprietary stylet necessary to operate the system as a component. A tip-location system and stylet comprise one product because they are designed to function together and one cannot function without the other.

44. The tied product is Bard's PICC. Bard has FDA approval to sell its tip-location stylets separately from its PICCs. These stylets are compatible with AngioDynamics' BioFlo PICC and with other competitors' PICCs as well. Yet Bard has refused and continues to refuse to sell the stylets separately from its PICCs.

45. The stylet is not a component of the PICC; Bard sought and received approval from the FDA to sell its stylets separately from its PICCs, and Bard has done so for use with AngioDynamics' PICCs. This demonstrates that it is not necessary to use the Bard stylet with a Bard PICC.

46. There is no legitimate business or other reason that Bard must tie its tip-location systems (including proprietary stylets) to its PICCs. Bard ties its tip-location systems to its PICCs for the sole purpose of eliminating competition in the sale of PICCs. Any justification Bard has for this tying is far outweighed by the anti-competitive effects in the market for PICCs.

47. Bard's tying the sale of its PICC tip-location systems to the sale of its PICCs therefore violates Sections 1 and 2 of the Sherman Act.

ANTITRUST INJURY

Harm to PICC Price Competition and Innovation

48. Bard's tying has unlawfully excluded substantial PICC competition, including suppressing price competition throughout the PICC market. It has enabled supra-competitive pricing for Bard's sale of its PICCs whether or not the hospital purchases the Bard tip-location

system. Bard's tying has also suppressed competitive choice and innovation, and has compromised patient welfare with its inferior PICCs.

49. Bard's tying has prevented competitors from selling to a substantial portion of the PICC market and helps Bard maintain its market power. Bard's conduct has caused anticompetitive effects in the PICC market.

50. Bard's tying has been very successful, allowing Bard to maintain a dominant position in the PICC market, exceeding 70 percent market share, while other competitors' sales and market shares have gone down. AngioDynamics and other competitors have thus been foreclosed from selling PICCs to a substantial share of the PICC market.

51. PICC purchasers requiring use of the superior Bard tip-location system have been coerced into buying Bard PICCs and have not been able to buy competitors' PICCs because Bard has refused to sell its tip-location system stylets single-sterile and instead ties them to its PICCs. Customer choice and innovation have thus been significantly reduced.

52. Bard's tying arrangement stifles innovation and harms patient welfare, preventing a large segment of the population from obtaining access to Angiodynamics' BioFlo PICCs, which have been proven to reduce thrombus accumulation, and reduce the reflux of blood into the catheter for valved PICCs, thereby reducing the risk of further complications.

53. As a result of Bard's market power in the PICC market, price competition in that market has decreased substantially. Because Bard has been able to capture and maintain market power in the PICC market, it has caused competitors to lose PICC sales and market share. As a result, AngioDynamics and other competitors have been foreclosed from a substantial share of the PICC market.

54. Bard's tying has caused antitrust injury nationwide. Purchasers have paid supra-competitive prices whether or not they have attempted to purchase Bard tip-location systems. By suppressing the market shares of its PICC competitors below 30 percent of the PICC market, Bard's competitors do not have sufficient shares to take enough PICC business away from Bard to make its supra-competitive pricing unprofitable, thereby forcing it to reduce that pricing to competitive levels available across the class of purchasers of Bard PICCs.

55. Bard has effectively coerced purchasers of its tip-location systems to purchase its PICCs. Unless they purchase Bard's PICCs, they are unable to obtain Bard's proprietary stylet to operate its tip-location systems. The only economically viable option for PICC purchasers who wish to use one of Bard's dominant and superior tip-location systems is to purchase their PICCs from Bard to obtain the stylet necessary for their operation. Purchasing Bard's stylet preloaded in a Bard PICC and additionally purchasing, for example, AngioDynamics' BioFlo PICC is not an economically reasonable or viable option. The purchaser would pay for two sets of PICCs when only one set was needed.

Suppression of the AngioDynamics Life-Saving PICC Technology

56. Despite their popularity for patient treatments over intermediate periods of time, PICC use is associated with a variety of complications, including infection, blood clotting, and line malfunction or blockage. Blood clotting can result in obstruction of a blood vessel, a condition called venous thrombosis.

57. Deep vein thrombosis ("DVT") occurs when a blood clot blocks a large, essential vein below the surface of the skin. Pulmonary embolism ("PE") occurs when a blood clot originating in another part of the body travels to and obstructs vessels in the lungs. Both conditions can be life-threatening and require immediate medical attention.

58. DVT and PE are together known as venous thromboembolism (“VTE”). In the United States, there are more than 900,000 VTE events per year, a rate that has not changed significantly in the past 25 years. However, because the risk of DVT and PE is closely correlated with aging, the impact of these conditions is expected to increase as the U.S. population ages.

59. DVT-related PE is the most common cause of preventable death in hospitalized patients, with more patients experiencing DVT in a given year than heart attack or stroke.

60. In 2008, in recognition of the high number of DVT and PE cases in the United States, the acting Surgeon General issued a “call to action” to reduce the number of DVT and PE cases. The Surgeon General asked the healthcare community to develop methods for combatting this problem, calling DVT and PE “a major public health problem” that “exact[s] a significant human and economic toll on the Nation.”

61. AngioDynamics has manufactured and sold PICC products in the United States since 2007. In 2012, AngioDynamics obtained FDA approval for a groundbreaking new PICC, which it markets as the BioFlo PICC. BioFlo PICC is manufactured using a proprietary material that resists the accumulation of blood components and thus impedes clot formation.

62. BioFlo’s technology is a permanent and “non-eluting” integral polymer. This means that it is not a coating or impregnated into the catheter. Instead, the Endexo Technology polymer is blended with carbothane thermoplastic polyurethane during the proprietary manufacturing process. Unlike a coating or impregnated material, this technology is present throughout the catheter material, including the outer surface, inner surface, and even the cut catheter tip. The combined material imparts the catheter shaft with protection against thrombus accumulation by creating passive surfaces. All other things equal, the BioFlo PICC reduces the

risk of serious and life-threatening patient complications including DVT and facilitates higher quality care at a lower cost.

63. A number of health-care institutions have studied the efficacy of BioFlo PICCs and have independently published or formally presented results in a scientific platform. These studies demonstrate the dramatic results of the use of BioFlo. As examples: the Cleveland Clinic noted that BioFlo PICCs reduced thrombosis by a factor of 6.2 overall; St. Rita's Medical Center in Lima, Ohio, noted a 73 percent reduction in catheter occlusions, 80 percent reduction in DVT, and 64 percent reduction in the cost of tissue plasminogen activator; and Flagler Hospital in St. Augustine, Florida, noted a 74 percent reduction in catheter occlusions and a 73 percent reduction in DVT.

64. The BioFlo PICC is available with PASV Valve Technology, which is AngioDynamics' patented valve designed to automatically resist backflow and reduce blood reflux on the inside of the catheter.

65. As such, AngioDynamics' BioFlo PICC with Endexo Technology is a life-saving, disruptive, and innovative product offering. It is the first PICC of its kind with the ability to significantly reduce thrombus accumulation and, for those PICCs with PASV Valve Technology, to reduce the reflux of blood into the catheter as well. It provides a safe, cost-effective, advanced technology designed to significantly improve patient outcomes.

66. When AngioDynamics introduced BioFlo PICCs to the U.S. market, it anticipated rapid adoption of the BioFlo technology, given its groundbreaking anti-thrombogenic properties, and a resulting increased demand for its PICCs. Actual adoption of BioFlo PICCs, however, has been severely limited due to Bard's tying arrangements.

67. Bard sells standard polyurethane PICCs. They do not contain any thrombo-resistant material. Bard has been unable to develop a thrombo-resistant material similar to the technology included in AngioDynamics' BioFlo PICCs, despite its efforts to do so. In addition, Bard catheters exhibit longer taper lengths (4-7cm), creating additional obstruction of blood flow through the vessels, further increasing complication risk.

68. In sum, Bard's PICCs have none of the technological advancements designed to improve patient outcomes that AngioDynamics' PICCs have and, in addition, have design features that increase the risk of complications.

69. During an earnings call in October 2013 (not long after BioFlo PICCs received FDA approval and began to gain traction in the market), Bard announced that it was developing a new thrombo-resistant PICC family of products and anticipated launching them in 2014, following FDA clearance.

70. In subsequent earnings calls in 2014 and 2015, Bard reported that the development of its thrombo-resistant PICCs had been delayed and that it had yet to submit any "new" catheter technology to the FDA for approval.

71. In a January 2015 earnings call, Bard described the thrombo-resistant PICCs it intended to launch as "coated PICCs." This thrombo-resistant coating has proven ineffective in achieving the reduced thrombus results of Endexo Technology, which is not a coating but rather a polymer added directly to the base polyurethane during the manufacturing process.

72. Among other things, coatings create an additional step in the manufacturing process, and they are ineffective in protecting cut surfaces. Coatings also elute into the blood stream, exposing patients to chemicals unnecessarily.

73. Endexo Technology does not suffer from any of these shortcomings. BioFlo PICCs benefit from a consistent manufacturing process, and the Endexo Technology in BioFlo PICCs cannot wear off, given that it is an integral part of the catheter itself, not a coating. This also means that it is present on the cut catheter tip and protects that surface.

74. In addition, in more recent earnings calls, Bard has not made any further reference to its efforts to develop a thrombo-resistant PICC family of products. Bard thus does not have any PICC products on the market that provide the type of reduced thrombus accumulation that AngioDynamics' BioFlo PICCs provide, and it does not appear that Bard is close to introducing any such PICCs into the market.

CLASS INJURY AND STANDING

75. Plaintiff and the Class of Bard PICCs have suffered injury of the type the antitrust laws were intended to prevent and flows from that which makes Defendants' act unlawful.

76. Plaintiff and the Class allege that Defendants' anticompetitive conduct has caused them to pay supra-competitive prices for Bard's PICCs. Such an injury is plainly of the type the antitrust laws were intended to prevent.

77. Defendants' misconduct has directly caused this injury to Plaintiff and the Class. Plaintiff and the Class are naturally motivated to enforce the antitrust laws because they had and have the natural economic self-interest in paying reasonable rather than supra-competitive prices.

78. Whereas Bard's competitor AngioDynamics, as noted, has pursued antitrust claims against Bard for its harm to competition in the PICC market, that lawsuit has not sought to recover for the injuries to the members of the Class, and denying Plaintiff and the Class a remedy in favor of a suit by Bard's competitor would be likely to leave a significant antitrust violation undetected or unremedied.

79. Any overlaps in the facts and issues between this action and the action that Bard's competitor AngioDynamics has brought do not concern the calculation of damages in the respective actions, which calculations involve conceptually and categorically different measures that pose no threat of duplicative recoveries.

CLASS ACTION ALLEGATIONS

Class of Direct Purchasers of Bard PICCs

Federal Rule of Civil Procedure 23(a)

80. Plaintiff ("Class Representative") is a representative of a Class of U.S. direct purchasers from Bard of its PICCs on or after March 31, 2014. "Purchasers" include in part hospitals, hospital systems, and clinics.

81. Prosecution of the claims of the Class as a class action is appropriate because the prerequisites of Rule 23(a) of the Federal Rules of Civil Procedure are met:

- (a) The number of members of the Class is in the thousands, and the members are therefore so numerous that joinder of all of them is impracticable. Joinder also is impracticable because of the geographic diversity of the members, the need to expedite judicial relief, and the Class Representative's lack of knowledge of the identity and addresses of all members.
- (b) There are numerous questions of law and fact arising from the tying restraint of trade which are common to the members of the Class. These include, but are not limited to, common issues as to (1) the existence of separate tip-location and PICC markets; (2) Bard's market power in both markets; (3) whether Bard has tied sales of its tip-location systems including proprietary stylet to the sales of its PICCs; and (4) whether the tying has caused antitrust injury to the members.

In addition, there are common issues as to the nature and extent of the injunctive and damage relief available to the members.

82. The Class Representative and its counsel will fairly and adequately protect the interests of the members of the Class. There are no material conflicts between the claims of the Class Representative and the members that would make class certification inappropriate. Counsel for the Class will vigorously assert the claims of the Class Representative and the other members.

Federal Rule of Civil Procedure 23(b)(3)

83. The prosecution of the claims of the Class as a class action pursuant to Rule 23(b)(3) is appropriate because (a) questions of law or fact common to the members of the Class predominate over any questions affecting only its individual members; and (b) a class action is superior to other methods for the fair and efficient resolution of the controversy.

Federal Rule of Civil Procedure 23(b)(2)

84. The prosecution of the claims of the Class as a class action pursuant to Rule 23(b)(2) is appropriate because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief, or corresponding declaratory relief, for the Class as a whole.

CAUSES OF ACTION

COUNT I

**Tying of Separate Products
in Violation of Section 1 of the Sherman Act**

85. Plaintiff realleges the allegations above.

Per Se Violation

Bard Ties Its PICC Tip-Location Systems to Its PICCs

86. Bard's tying of its PICC tip-location systems with proprietary stylet to its PICCs during the relevant period is a *per se* violation of Section 1 of the Sherman Act. Bard's tip-location system with proprietary stylet is the tying product. Bard's PICC is the tied product.

87. The tip-location systems, including proprietary stylets, and the PICCs are separate products sold in separate markets. The FDA has approved Bard's sale of the stylet single-sterile. Bard sold the stylet single-sterile on only one occasion, when the Cleveland Clinic demanded it. Bard has otherwise refused to sell the stylet single-sterile.

Bard Coerces Purchasers to Buy Its PICCs

88. Bard leverages its control of its proprietary stylet, which is necessary to operate its tip-location system, to coerce purchases of its PICCs by refusing to sell the stylet separately from the PICC. By doing so, Bard has conditioned the purchase of its tip-location systems upon the purchase of its PICCs, depriving purchasers of these systems of the option of buying AngioDynamics' BioFlo PICCs and the PICCs of other competitors.

Bard Possesses Market Power in the Tip-Location Market

89. At all times relevant to this action, Bard has had substantial market power in the tip-location market. Bard's Sherlock 3CG system is the only one on the market that provides ECG tip-location technology, navigation technology, and ultrasound technology. This combination of

technologies provides the highest quality in PICC placement, thus providing the greatest ease of use and accuracy for clinicians.

90. Bard has a substantial share of the tip-location market and has had a significant share for some time. Bard's current share of the market exceeds 70 percent.

91. There are high barriers to entry in the tip-location market, including both technological and regulatory barriers. As one would expect given such conditions, there has been little entry in the market.

92. Given its dominant position in the tip-location market, Bard possesses market power sufficient to coerce customers into purchasing the tied product, Bard's PICC.

Bard's Conduct Harms PICC Competition in the Tied Market

93. Bard's refusal to sell its proprietary stylets necessary to operate its tip-location systems single-sterile has foreclosed purchasers who prefer AngioDynamics' and other competitors' PICCs from pairing them with Bard's superior tip-location systems.

94. Instead, purchasers that want a Bard tip-location systems must purchase Bard PICCs to obtain the stylet necessary to operate the tip-location systems. This hampers competition in the PICC market to the detriment of purchasers and Bard competitors.

95. Bard has substantially suppressed price competition and maintained its market power in the PICC market and has been able to charge pricing above the competitive levels that would have been available across members of the class with full and vigorous PICC competition.

96. Although AngioDynamics' BioFlo PICCs are far superior to Bard PICCs and provide significant and superior health benefits, Bard's anticompetitive tying stifled sales of BioFlo PICCs and has denied purchasers competitive choice and harmed patient outcomes.

97. Bard's conduct has thus harmed price and quality competition in the PICC market, enabling Bard's supra-competitive pricing.

Bard's Tying Impacts a Substantial Amount of Interstate Commerce

98. PICC sales in the United States total approximately \$400 million per year. Bard accounts for the vast majority of sales in the PICC market. PICCs are widely used in hospitals and other medical care facilities across the United States to administer medicines to thousands of patients. Bard's tying thus impacts a substantial amount of interstate commerce.

Rule-of-Reason Violation

99. If Bard's tying is not *per se* illegal, it nevertheless violates Section 1 of the Sherman Act under the rule-of-reason doctrine because it is an unreasonable restraint of trade.

100. There is no legitimate business or other pro-competitive justification for Bard's tying of its tip-location system to its PICC. Bard has FDA approval to sell its stylet separately from its PICC, and Bard has sold them separately on at least one occasion. Its refusal to do so otherwise is designed to eliminate competition in the PICC market. Any justification Bard may have for its tie is far outweighed by the anti-competitive effects in the PICC market.

COUNT II

**Monopolization of the PICC Market
in Violation of Section 2 of the Sherman Act**

101. Plaintiffs reallege the allegations above.

102. Bard has monopolized the PICC market for the sale of PICC catheters. Bard has market power in the PICC market and has willfully maintained that market power.

103. Bard has thereby substantially harmed competition in the PICC market and has charged supra-competitive prices to members of the Class.

104. As a result of Bard's conduct, members of the Class purchasing Bard's PICC catheters have suffered antitrust price injury.

105. Bard's conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2.

PRAYER FOR RELIEF

106. Plaintiff and the Class pray that this Court certify the Class and enter judgment on their behalf against Defendants and decree as follows:

- (a) Defendants have engaged in conduct in violation of Sections 1 and 2 of the Sherman Act and have harmed competition and imposed antitrust price injury on members of the Class in their businesses or property, as well as suppressed life-saving competitive PICC choice.
- (b) Plaintiff and the Class recover damages sustained, and a judgment in favor of Plaintiff and the Class shall be entered against Defendants, in an amount to be trebled in accordance with such laws, including Section 4 of the Clayton Act;
- (c) Defendants, their subsidiaries, affiliates, successors, transferees, assignees, and the respective officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf, shall be permanently enjoined and restrained from continuing the illegal conduct alleged herein;
- (d) Plaintiff and the Class shall be awarded pre-judgment and post-judgment interest, and such interest shall be awarded at the highest legal rate from and after the date of service of the initial complaint in this action;
- (e) Plaintiff and the Class shall recover their costs of this suit, including reasonable attorneys' fees as provided by law; and

- (f) Plaintiff and the Class shall receive such other or further relief as may be just and proper.

JURY TRIAL DEMANDED

Plaintiff demands trial by jury.

Dated: March 31, 2020

Respectfully submitted,

By: /s/ Christopher V. Fenlon

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